

DEPARTMENT OF HEALTH
WASHINGTON STATE BOARD OF PHARMACY
MEETING MINUTES

August 31, 2006
CenterPoint Corporate Park Conference Center
20809 72nd Ave South
Kent, WA 98032

CONVENE

Chair Asaad Awan convened the meeting at 9:02 a.m. on August 31, 2006.

Board Members present:

Donna Dockter, RPh
Gary Harris, RPh
Rebecca Hille, Vice-Chair
Rosemarie Duffy, RN
Susan Teil-Boyer, RPh
George Roe, RPh

Staff Members present:

Joyce Roper, Assistant Attorney General
Lisa Salmi, Acting Executive Director
Tim Fuller, Pharmacy Consultant
Andy Mecca, Pharmacy Consultant
Grace Cheung, Chief Investigator
Joseph Honda, Pharmacist Investigator
Doreen Beebe, Program Manager
Greg Rice, Program Support

August 31, 2006

Open Meeting

CONSENT AGENDA

- 1.2** Pharmacy & Other Firm Application Approval
 - Report of opened and closed pharmacy firms from 06/21/06 thru 07/25/06
- 1.5** Collaborative Drug Therapy Agreement Acceptance
 - Suk Pui To – Anti-Malarial Medication
 - Suk Pui To – Motion Sickness
 - Suk Pui To – Altitude Sickness
- 1.7** Sample Distribution Request
 - Peninsula Community Health Services – Bremerton

Items 1.1- Pharmacist License Application Approval; 1.4- Pharmacy Tech Training Program Approval were deleted from the consent agenda. **MOTION:** George Roe moved to accept 1.2, and 1.7, Rebecca Hille second. **MOTION CARRIED 7-0.**

Item 1.3 Pharmacy Technician Training Program – Requests from Ericka Borg and Elizabeth Fisher were removed from consideration. Their technician training programs were approved at the July business meeting. **MOTION:** Gary Harris moved to approve technician training programs for

- Theresa R Hagen
- Jargriti Gupta
- Carlotta Causey

George Roe second. **MOTION CARRIED 7-0.**

Item 1.5 Collaborative Drug Therapy Agreement Acceptance. **MOTION:** Donna Dockter moved to accept Collaborative Drug Agreements stipulating that the agreements apply to the specific pharmacist named in the protocols. Susan Teil-Boyer second. **MOTION CARRIED 7-0.**

Item 1.8 Board Minute Approval. The following changes requested to the July 20th business meeting minutes.

1. Correction: Offsite Pharmacy Practice – Motion to read: stipulated practice approved to allow pharmacists to engage in the practice of pharmacy as long as the pharmacist works for a pharmacy licensed in Washington State.
2. Correction: Board Reports – Donna Dockter attended a Washington State Pharmacy Association meeting in which she participated in a presentation on medication error prevention.
3. Electronic Prescription Transmission System – Condor Pharmacy System – strike from page 10 – “She also questioned what ICD9 is.” Donna Dockter requested Condor Pharmacy Systems to remove ICD9 and/or add a statement of purpose on the electronic prescription form.

MOTION: Susan Teil Boyer move for the approval of the July 20th meeting minutes with the above reference changes. Rebecca Hille second. **MOTION CARRIED 7-0.**

Automated Drug Distribution Devices

Tim Fuller summarized the suggested changes presented to the Board at the July 20th Rules Hearing regarding WAC 246-865-060 Automated Drug Distribution Devices. Mr. Fuller highlighted the changes focusing on those that were identified as substantive. A copy of the original language and the proposed rule with changes were reviewed by the Board. No public comments will be accepted during this agenda item.

The Board’s options were:

- Adopt the rule as proposed;
- Adopt the rule with housekeeping edits (non-substantive);
- Adopt the rule with all edits including substantive changes (substantive changes may be challenged within 60 days; or
- File a continuance to hold a 2nd hearing to receive additional public comments.

Amended language offers clarity, provides reference to existing rules defining health care and medical facilities (substantive), further characterizes a pharmacist’s oversight, requires standards for medication waste (substantive); and verification of controlled substances to include security support systems (substantive).

Stocking in nursing homes – concerns were raised that other health professionals needed to participate in the stocking of these machines, which is limited to pharmacy personnel only [(WAC 246-872-030 (5))]. Joyce Roper offered that this discussion should be coordinated with the Nursing Care Quality Assurance Commission (NCQAC).

Susan Teil Boyer stated that the Board has been working on this rule for sometime and that the current rules on the books are insufficient and for the majority of situations (hospitals) the proposed rules are a good fit.

MOTION: Susan Teil Boyer moves for approval of the rule language as presented with all suggested changes and acknowledges the need to coordinate discussions with the NCQAC regarding the issue of nursing home facilities and long-term care pharmacies. Donna Dockter second.

MOTION CARRIED 7-0.

REPORTS

Acting Executive Director

Lisa Salmi reported on the following:

- The Department of Health will host the Annual Board/Commission/Committee Meeting on September 28-29, 2006. The afternoon of the 28th is for leadership. The dinner and evening session on the 28th is open to all Board Members, as well as the meeting on September 29th. The focus of this meeting is patient safety.
- Tim Fuller and Ms. Salmi met with the representative of the Department of Health (DOH) Immunization Program, to discuss including pharmacists in the Department's Vaccines for Children's Program, and the Childs Profile System. Also met with representatives of Department of Social and Health Services to discuss pharmacists' involvement in administering immunizations and vaccinations, and obtaining reimbursement for these services. Discussed reimbursing pharmacists for Tuberculosis testing.
- Pharmacy Investigator Bill Kristin and Joe Honda recently completed inspections of pharmacies to assess compliance with the Poison Prevention Packaging Act. The inspections resulted in an examination of 1371 prescriptions, and found 30 that were in violation of the Poison Packaging Act requirements. The US Consumer Product Safety Commission will follow up on all the prescriptions that were in violation.
- Staff has been meeting with representatives of the CAVU Corporation. The DOH has contacted CAVU for a new licensing system. We are currently discussing issues around data conversion.
- Interviews for the Executive Director position were held on August 30th. Three candidates applied for the position. The interview panel consisted of Asaad Awan, Rebecca Hille, George Roe, Bonnie King, Steve Saxe and Lisa Salmi.
- The quarterly Investigators Meeting is scheduled for September 6th and 7th, in Tumwater. Rosemarie Duffy will be in attendance.
- The next meeting of the Methamphetamine Workgroup will be held on October 18th, in Tumwater. Donna Dockter is the Board representative to the Workgroup. The agenda for this meeting should be out soon.
- The recruitment for the Central Washington Investigators Position will be open during the week of the 28th. Anticipate holding interviews during the last week of September.
- Bob Horner will be filling the Section 4 Credentialing Manager Position on a non-permanent appointment for one year.
- The Precursor Investigators Position will be temporarily filled by Jim Doll, until we a permanent replacement is hired. Randy Flett retired from state service on August 2nd. Jim Doll is also managing the activities of the Methamphetamine Workgroup. Anticipate recruiting for this part time position will be in mid-September.
- Jennifer Wells has promoted to another department within state service. Greg Rice has been hired as a temporary employee until a permanent employee is hired.

Consultant Pharmacist/Investigators

Tim Fuller reported on the following:

- NCQAC Executive Director, Paula Meyers, and a nurse from the Superintendent of the Public Instruction (SPI) and Mr. Fuller met to discuss revisions of SPI's oral medication guidelines to comply with new asthma law. The real change was in terms of looking at an alternative to secure substantially constructed place for medications to be stored. Mr. Fuller will update the Board

Andy Mecca reported on the following:

- Mr. Mecca will begin scheduling stakeholder meeting to discuss scheduling SOMA as a C4.
- Mr. Mecca will present information on law changes and history on prescription legibility at the Health Professions Quality Assurance Boards, Commissions and Committees conference on September 29th.

Chief Investigator

Grace Cheung reported on personnel issues and activities that may impact the number of inspections completed by the investigative staff. She will also set the schedule for the quarterly investigators' meetings for 2007 once the Board identifies its meeting dates for next year.

PRESENTATIONS

Disciplinary Sanction Guidelines and HB2974

Karl Hoehn, Health Professions Quality Assurance (HPQA) Legal Services Manager presented to the Board the Secretary of the Department of Health's *Disciplinary Sanction Guidelines* and discussed implementation of House Bill 2974 – Mandatory Summary Suspension. Disciplinary Process Update

Mr. Hoehn updated the Board on three major topics regarding disciplinary processes and process improvements.

1. Update on non-compliance procedures.
2. Sanction guidelines in effect for all Secretary authority health professions.
3. Developments with HB2974, which changes parts of the Uniform Disciplinary Act (UDA).

Non-Compliance

Mr. Hoehn acknowledged that the Board of Pharmacy was the first Board to adopt the new non-compliance process last year. The process simplified and expedited the course of action when someone is out of compliance with an order. The process was intended to eliminate duplicate steps without jeopardizing due process. When there is substantial non-compliance with an order this process can be used to fast track hearings (within 4 weeks) and put the license on suspension if they fail to comply.

Non-compliance with fines or cost recovery may now be assigned to a debt collection agency. The compliance officer will monitor compliance. Issues of non-compliance will be presented to the Board for determination if the fast track process is to be used.

No longer restricted to orders issued after May 2005.

Sanction Guidelines

The guidelines consider broad categories of conduct rather than specific legal violations. Sanctions are based on severity of conduct and consider aggravating and mitigating factors.

Seven Conduct Categories:

1. Sexual Misconduct
2. Abuse of Patients – Emotional or Physical
3. Drug Diversion
4. Felonies
5. Practice Below Standards
6. Misuse of Drugs
7. Non-Compliance

The worksheet provides the Reviewer an opportunity to document type and severity of conduct, aggravating and mitigating factors, prior disciplinary history, recommendation and additional conditions. Mr. Hoehn asked that the Board review the guidelines and provide feedback on how these compare with what the Board uses and what they feel is appropriate action in various cases. He suggested that the Board might consider using closed cases and see how these guidelines would be applied.

HB2974

- Mandatory Reporting
- Persons prohibited in another jurisdiction cannot be licensed here.
- Mandatory Summary Suspension – for persons prohibited in another jurisdiction for conduct that would be substantially similar to unprofessional conduct in WA, they must be summarily suspended until the issue can be fully considered. An inter-disciplinary Case Management Team reviews these cases with participation from a member of the Board.

Opioid Presentation

Andy Mecca provided background information on the interagency work group formed in 2005 to development of opioid dosing guidelines for chronic non-cancer pain. The draft guideline was provided for Board review. Dr. George Heye from the Medical Quality Assurance Commission and Andy Mecca served as liaisons for the Department of Health and the work group. The goal of the presentation is to provide information to Health Boards and Commissions and elicit their comments to assist with the future direction of the guidelines.

Dr. Jamie Mai, Pharmacist Consultant with the Department of Labor and Industries (L&I) reiterated that the guidelines are still a draft and would not be finalized until early 2007.

L&I, in managing worker compensation claims, began to receive reports of opioid related deaths. They discovered that there was an increase in opioid related deaths after 1996 and daily doses on average increased from 83 mg per day to 132 mg in 2002. This appeared to be a nationwide trend.

The guidelines are designed to give provider guidance to ensure that treatment with opioids is safe and effective. Dr. Mai stated that once the guidelines are published the goal is to provide education for a year before taking more restrictive action.

DISCUSSIONS

Pseudoephedrine Packaging Exemption Request

Lisa Salmi presented the request from Leiner Healthcare for a waiver to the 3 grams per package limit. An exemption to the packaging limits is permitted per RCW 69.43.130 if the product meets specific requirements listed in the law. The Leiner Healthcare products associated with this request

do meet these requirements. Staff recommends that the Board approve the exemption. Approval does not violate the new federal law.

MOTION: George Roe moves to grant exemption requested by Leiner Healthcare. Donna Dockter second. **MOTION CARRIED 7-0.**

2007 – Disciplinary Hearing/Business Meeting Schedule and 06-07 Travel

2007 Meeting Dates

- January 25th and 26th - Tumwater
- February 28th (Planning Meeting) - Kent
- March 1st and 2nd* - Kent
- April 12th and 13th* - Tumwater
- May 17th and 18th* - Vancouver WA
- July 26th and 27th* - Kent
- September 6th and 7th* – Spokane, if budget permits
- October 25th and 26th* - Kent
- December 13th and 14th* - Kent

*Disciplinary Hearing Dates

Note: Washington State Pharmacy Association Tri-State meeting in June 2007 – coordinate with WSPA – proposed attendance by Chair and Vice-Chair.

MOTION: Rebecca Hille moved to approve meeting dates for 2007 (as documented above). Susan Teil-Boyer second. **MOTION CARRIED 7-0.**

Travel Plans 2006-2007

- November 4 – 5, 2006 – NABP --- George Roe, Lisa Salmi & Grace Cheung
- May 19-22, 2007 - NABP ---Not considered out-of-state travel
- June 24-27, 2007 University of Utah School of Alcoholism & Other Drug Dependencies --- Rosemarie Duffy & Gary Harris
- DEA – To be announced

Correspondence

Board reviews the National Association of Boards' of Pharmacy report of the 2005-2006 Committee on law Enforcement Legislation.

Pharmacy Technicians' National Standardized Certification Exam – Draft Rule Proposal

The Board discussed proposed amendments to WAC 246-901-030 and 060 and reviewed stakeholder comments regarding exam requirements for pharmacy technician certification.

Tim Fuller provided background and a summary of issues discussed the stakeholder meetings held in Kent and Spokane earlier this year.

Highlights

- Two national standardized certification exams available – ExCPT & PTCB exam
- Access to exams issue for Pharmacy Technician applicants.
- 90% -average scores of Washington Pharmacy Technicians taking PTCE – national average 80%.

- PTCB exam taken by over 250,000 pharmacy technicians.
- ExCPT taken by over 20,000 pharmacy technician.
- Grandfathering clause – proposed for existing WA certified pharmacy technicians.

Mr. Fuller asked the Board if they wish to approve more than one exam and if they wished to name the exams in the rule or approved that language as “Board-approved national standardized certification examination.”

Donna Dockter questioned the need to include the word “certification” in the proposed rule language as part of the identifier of the requirement for a Board-approved national standardized exam. Ms. Dockter was concerned that this may limit the Board’s ability to approve national standardized exams in the future if the word “certification” is not included in the title. Ms. Teil-Boyer and Ms. Duffy felt the word “certification” clarifies the purpose of the exam.

MOTION: Rosemarie Duffy moved to approve the proposed rule language for WAC 246-901-030 and 060 as submitted. Susan Teil-Boyer second. **MOTION CARRIED 7-0.**

Joyce Roper suggested that the effective date of the rule could be established at the time of the hearing/adoption of the rule.

Washington Recovery Assistance Program for Pharmacy (WRAPP)

Representatives Ruther Kerschbaum, Doug Beeman, Leon Alzola and Rod Shafer, CEO of WSPA appeared before the Board to propose a budget increase for the WRAPP program for services provided under a four year contract with the Department signed in June 2005. The program requested \$40,576 increase - \$10,000 per year increase over a four-year period to cover expenses for salary, program management, satisfaction surveys, audits and increase education of clients. A copy of WRAPP’s budget was distributed.

Ms. Kerschbaum expressed concerns about the hardship of passing on the costs of the WRAPP monitoring program to clients, specifically pharmacy technician. Clients currently pay for urine analysis and their treatment programs. WRAPP currently has 66 clients – 47 pharmacists and 19 pharmacy technicians. Approximately \$1000 per year cost to the Board for each participant.

The Board acknowledges that the WRAPP program has been successful and well managed. The cost of the program is relatively small compared to the services provided to the state, pharmacists and public safety.

Lisa Salmi explained that to grant the proposed increase the Board will need to cut discretionary spending; such as salaries, travel, meeting room expenses, etc.

Donna Dockter suggested that clients pay an annual fee with the understanding that technicians should pay no fee or a reduced fee to prevent any barriers to their participation in the program.

Ms. Salmi reminded the Board that we will be developing a new biennium budget in July 2007 and could consider increasing the WRAPP budget at that time as well. The

Information Requested by the Board

- Legislative Request for Dedicated Funds
- Delineation of WRAPP budget
- Review discretionary spending for cuts

MOTION: Rebecca Hille moved to postpone the decision until the October Board meeting. Susan Teil-Boyer second. **MOTION CARRIED 7-0.**

Executive Session – Closed Session

The Board adjourned for Executive Session at 12:00 p.m. to discuss Emergency Preparedness and Response, including items exempt from public disclosure under RCW 42.56.420, and personnel issues.

The Board reconvened at 1:00 p.m.

Pharmacist Responsibilities Proposed Rule Language

The Board discussed the proposed language regarding a pharmacist's responsibilities when presented with a lawful prescription and the next steps. No public comments were accepted during this agenda item.

Chair Asaad Awan invited Christine Hulet, the Governor's Health Policy Advisor and Marty Brown, the Governor's Legislative Director to update the Board on the stakeholder work in which they facilitated and present alternative rule language.

Ms. Hulet thanked the Board for allowing them to speak on behalf of Governor Gregoire. Marty Brown and Ms. Hulet acknowledged the Board's efforts and the volume of constituent and media interest in the rule. Ms. Hulet briefly discussed the negotiations with Dona Dockter; Don Downing, University of Washington School of Pharmacy; representatives from Planned Parenthood, Washington State Pharmacy Association, the Northwest Women's Law Center, the Department of Health and other resulted in language that the Governor feels provided a balance between patient access and it recognizes the important role of pharmacists in our health care system and patient safety.

Christina Hulet read into record a letter from the Governor issued to the Board recommending the approval of the alternative rule language. A copy of the alternative rule language was distributed to members of the Board and highlighted by Ms. Hulet.

MOTION: Susan Teil-Boyer moved to reconsider the proposed rule language accepted at the June 1 meeting. Rebecca Hill second. **MOTION CARRIED 7-0.**

The Board was instructed by Chair Awan to have a brief discussion on the rule language provided by the office of Governor Gregoire.

Donna Dockter shared her concerns about the proposed language. She stated that the language does not clearly state the Board's expectation of a pharmacist when they do not dispense a legal prescription. Ms. Dockter indicated that the list of exceptions for when a pharmacist would not dispense is not inclusive, which she acknowledged that it would not be possible given the many aspects of the practice of pharmacy. Donna Dockter stated that exception (1)(c) did not adequately address the compounding of drugs that does not require specialized equipment or expertise but may not be done for sound business reasons or special services such as filling insulin syringes.

Donna Dockter requested clarification on the second sentence of the proposed rule which begins “Pharmacies have a duty to dispense...” Pharmacists dispense prescriptions not pharmacies. She asked if approved as written who will be disciplined.

Gary Harris stated that he supports the Governor’s proposed language. In response to the many examples given by Ms. Dockter, Mr. Harris felt that the Board would not pursue disciplinary action against the pharmacist.

Susan Teil-Boyer suggested changing the word “Pharmacies” to “Pharmacists” in the second sentence of the rule. Ms. Teil-Boyer acknowledged that this has been the toughest issue that the Board has dealt with in her seven-years of service on the Board. She was in agreement with several of the issues presented by Ms. Dockter; however, to move forward she stated she would support the alternative rule language.

MOTION: George Roe moved to approve the alternative rule language changing “Pharmacies” to “Pharmacists” in the second sentence of the rule. Rebecca Hille second. **MOTION CARRIED 6-1**, Donna Dockter opposed.

Steven Saxe, DOH Director of Facilities and Services Licensing (former Board of Pharmacy Executive Director) briefed the Board on the next steps in the rules process.

Standards of Professional Conduct – Sexual Misconduct – Draft Rule Proposal

Doreen Beebe provided background information on the draft rules presented for consideration by the Board. In addition, a summary of stakeholder comments were provided to the Board for review.

Donna Dockter shared with the Board some of the discussion from the July 20th stakeholder meeting and the potential need for much of the language contained within the rule with the changing practice of pharmacy.

Joyce Roper offered to work with Lisa Salmi in developing amendments to the draft language to incorporate the Board’s concerns about restricting providers from engaging in a personal relationship with patients/clients within two years after the provider-patient/client relationship has ended. The Board asked to focus on the abuse of patient trust and the imbalance of power/influence rather than a defined two year time period.

MOTION: Rebecca Hille moved to approve the proposed rule language with changes made by Joyce Roper and Lisa Salmi regarding the two year prohibition. Rosemarie Duffy second. **MOTION CARRIED 7-0.**

Pharmaceuticals from Households: A Return Mechanism (PH:ARM)

Board Pharmacist Investigator Stan Jeppesen updated the Board on the PH:ARM pilot project. In addition, the Board was asked to approve the guidelines developed for use by pharmacies in developing policies and procedures for participation in the pilot and authorize staff to approve these protocols.

Highlights

- Model project – 1st of its scope in the nation
- Grant money available if the pilot begins October 1st

- No controlled substances are being collected at this time
- Need protocol to state specific location of collection units
- 24 sites participating in project
- Contracted with the Waste Division Plant in Spokane for disposal
- Anticipated that the pilot will take in over 80,000 lbs of household pharmaceutical waste per year statewide
- Recommendation to change “should” to “shall” in guidelines

MOTION: Rebecca Hille moved to approve the guidelines with recommended changes. Susan Teil-Boyer second. **MOTION CARRIED 7-0.**

OPEN FORUM

- In response to an inquiry from the audience, Lisa Salmi stated Asaad Awan’s position on the Board is open for recruitment. Dr. Awan is eligible to apply for a second term.
- The Board received two comments regarding the pharmacist responsibilities rule – both were in support of a pharmacist choice of personal conscience.

PRESENTATION OF AGREED ORDERS

Adjournment

There being no further business, the Board adjourned at 2:37 p.m. They will meet again on October 27, 2006 in Spokane, Washington.

CLOSED SESSION – Case Presentations.

September 1, 2006 – Disciplinary Hearing – Cancelled

*Respectfully Submitted by:
Doreen E. Beebe, Program Manager*

Approved on October 27, 2006

*Dr. Asaad Awan, Chair
Board of Pharmacy*